

REMARKS

I. Status of the Claims

Claims 1-5, 7, 8, 10, 11, 13-21, 23, 24, and 28-32 are pending. Claims 1, 17, 20, 23, and 24 are in independent form. The claims have not been amended and Applicants' arguments set forth in the Amendment dated October 7, 2007 are maintained and incorporated by reference herein.

II. Information Disclosure Statement

Pursuant to the Examiner's comments at page 2 of the Office Action, the patent and non-patent literature referenced in applicants' previous responses is cited on an Information Disclosure Statement submitted herewith. The Examiner's consideration thereof is respectfully requested.

III. Rejections Over Prior Art Based On Cherukuri In View Of Le

1. Claims 1-5, 7-8, 10-11, 13-14, 17, 20, and 23-24 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 5,284,659 ("Cherukuri") in view of WO 99/579427 ("Le").

2. Claims 18-19 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Cherukuri in view of Le, further in view of U.S. Patent No. 4,517,205 ("Aldrich").

3. Claims 15-16, 21, and 28 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Cherukuri in view of Le, and further in view of U.S. Patent No. 6,004,538 ("Hughes.")

A. Argument

The combination of Cherukuri and Le is arbitrary, and one of ordinary skill in the art would not randomly replace one “bio-effecting agent” with another.

The above rejections 1-3 rely, at least in part, on the assertion that one of skill in the art allegedly would have had motivation *to utilize an acidulent in Cherukuri’s example as the bio-effecting agent in place of the breath freshener if one desired to treat xerostomia and dry mouth or reduce plaque on teeth* (Office Action, page 5). Purportedly, *a skilled artisan would have reasonably expected success since Cherukuri teaches various bio-effecting agents may be used including antigingivitis agents and Le teaches that acids reduce plaque, i.e. having an antigingivitis activity* (Office Action, page 5).

In the Response to Arguments, the Examiner alleges: *Firstly, the motivation to utilize bioeffecting agents comes from the primary reference itself. Cherukuri teaches the use of bio effecting agents such as breath fresheners, breath deodorants, antigingivitis agents. Le provides the motivation to utilize acidulents specifically. Le teaches acidulents are known in the art to treat xerostomia, reduce plaque on teeth (this provide[s] an antingingivitis property since the reduction of plaque reduces the likelihood of gingivitis from occurring), and to enhance, and improve flavor release.* (Office Action, pages 6-7).

A Declaration of Dr. Stephen Moss is submitted herewith. Dr. Moss is an expert in dentistry, and shows that there would have been no reason related to dentistry to combine Le with Cherukuri. Le teaches the use of acids to “reduce plaque” only in

connection with a chewing gum containing an abrasive. It is the polishing of the teeth by the abrasive chewing gum that removes plaque. Edible acids do not have antigingivitis activity or any physical or chemical effect on plaque. Therefore, it is clear that there would have been no reason to combine Cherukuri and Le, based on dentistry, and thus these rejections should be withdrawn.

IV. Rejections Based On Bealin-Kelly In View Of Hanke II

4. Claims 1-5, 7-8, 13-18, and 23 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,306,429 (“Bealin-Kelly”) in view of WO 97/06695 (“Hanke II”).

5. Claims 20-21 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Bealin-Kelly in view of Hanke II further in view of National Institute of Dental and Craniofacial Research, NIH publication, June 1999.

6. Claim 19 has been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Bealin-Kelly in view of Hanke II further in view of US Patent No, 6,099,880 (“Klacik.”).

A. Argument

The above rejections 4-6, based on Bealin-Kelly, in view of Hanke II and other secondary references, should be reconsidered at least because there is insufficient disclosure in Bealin-Kelly to read on the claimed “lipid or surfactant present in an amount sufficient to moisten, coat or lubricate the oral cavity” concentrated in a region having a surface on the exterior of a hard candy product.

The Response to Argument suggests that the liquid fill region disclosed in Bealin-Kelly could be reconfigured as a region on the surface of a product based on the

disclosure of Hanke II, because Bealin-Kelly, col. 4, line 56, says that “the filling can be a solid” (Office Action, page 14). However, the ingredients the Examiner identifies as oral comfort ingredients, phospholipids such as lecithin, are disclosed only in the context of forming a liquid center (see col. 4, lines 64 to col. 5, line 25; col. 6, lines 40-43).

Therefore, the Examiner has not identified a lipid or surfactant oral comfort ingredient arranged with a surface on the exterior of the product, as claimed, and thus these rejections should be withdrawn.

1. The Functional Effect of the Claimed Hard Candy Product is Surprising and Unexpected

The Office Action argues that acidulents were used in the prior art to cause salivation (page 4) (which is, in any event, admitted prior art). In support of the combination of references, the Office Action further argues that the cited NIH publication “teaches sucking on sugarless candies, particularly ones that contain citrus and mint, [to] treat xerostomia.” However, the claimed product attacks xerostomia in a novel way, concentrating an acidulent in one region of the product to enhance oral manipulation, while providing an oral comfort component in a separate region of the product. Moreover, customers recognized that the product had improved functionality, compared with known candies. The attached Declaration of Donald L. Mayer, an expert in marketing, is evidence that consumers perceived the AQUADROPS® Hydrating Mouth Drops product to function differently from other products available on the market. This conclusion is based on the incidence of consumer calls relating to the functionality of the product (as compared to more generic customer responses, for example). It is believed the claims are allowable in light of this additional evidence.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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